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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,791	08/10/2001	Muhammad A. Sharaf	442211	7448

7590 04/07/2005

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EXAMINER
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CHOI, LING SIU

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/927,791

Applicant(s)

SHARAF ET AL.

Examiner

Ling-Siu Choi

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1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,8-13 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 10-13 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 and 19-21 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. This Office Action is in response to the Amendment filed January 12, 2005. Claims 3-7 and 14-18 were canceled and claims 19-21 have been added. The Amendment made on claim 8 is supported on lines 16-18 of page 11 and new claims 19-20 are supported on lines 1-3 of page 12. In view of the Amendment, claims 8-9 are allowable over Smith et al. (US 5,747,249) and Ansorge et al. (US 5,912,118). Since claim 9 is objected, the present Office Action is made as non-final.

2. Claims 8-9 are allowable because claims 8-9 are drawn to a calibration standard comprising the use of **at least four polynucleotides** each having **different known length** and each being labeled with a **different fluorescent dye** having a distinctive spectral profile having a peak. However, such limitations are not reflected on Groups I and V. Thus, Group I and V will not rejoined with Group IV (claims 8-9). If the non-elected claim is canceled and the following objection is obviated, the application could be passed to issue.

### *Claim Objections*

3. Claim 9 is objected to because of the following informalities: claim 9, lines 1-2, "the fluorescent labeled at least four polynucleotides" is suggested to be changed to -- the fluorescent dye labeled at least four polynucleotides--.

Appropriate correction is required.

*Allowable Subject Matter*

4. Claims 8-9 and 19-21 are allowable over the closest references: Smith et al. (US 5,747,249) and Ansorge et al. (US 5,912,118).

<b>Calibration Standard</b> for a fluorescent polynucleotide separation apparatus, comprising
<b>at least four polynucleotides of different known length</b> each polynucleotide labeled with a different fluorescent dye having a distinctive spectral profile having a peak
wherein the lengths of the polynucleotides differ from one another such that, upon electrophoretic separation, the peak of the spectral profile of any one of the dyes does not significantly overlap the peak of the spectral profile of any of the other dyes

(summary of claim 8)

Smith et al. disclose a method to separate and detect tagged polynucleotide, comprising (a) providing a plurality of polynucleotides, each being tagged with a fluorophore, (b) resolving to separate one of the plurality of tagged polynucleotides from other tagged polynucleotides differing by a single nucleotide using an electrophoretic procedure capable of resolving tagged polynucleotides differing by a single nucleotide, and (c) detecting the resolved tagged polynucleotides by means of the fluorophore, wherein the tagged polynucleotides are obtained from one of a set of primer extension reactions in which each of the tagged primer oligonucleotides used in one of the sets is distinguishable by its spectral characteristics from the tagged primer oligonucleotides used in the other sets (claims 1 and 8). However, Smith et al. do not teach or fairly suggest a calibration standard comprising the use of at least four

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polynucleotides each having **different known length** and each being labeled with a **different fluorescent dye** having a distinctive spectral profile having a peak.

Ansorge et al. disclose a method to sequence nucleic acids, comprising (a) providing a mixture of labeled nucleic acid fragments of different length with fluorescent dyes, (b) separating the labeled nucleic acid fragments according to size by gel electrophoresis, and (c) determining the nucleic acid sequence by labeling the individual fragments (col. 2, lines 28-40; col. 6, lines 36-40; claims 6, 9, 12). However, Ansorge et al. do not teach or fairly suggest a calibration standard comprising the use of at least four polynucleotides each having **different known length** and each being labeled with a **different fluorescent dye** having a distinctive spectral profile having a peak.

In light of the above discussion, it is evident as to why the present claims are patentable over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ling-Siu Choi whose telephone number is 571-272-1098.

If attempt to reach the examiner by telephone are unsuccessful, the examiner=s

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supervisor, David Wu, can be reach on 571-272-1114.

*L. S. Choi*

**LING-SUI CHOI  
PRIMARY EXAMINER**

April 4, 2005